UNITED STATES DISTRICT COURT

NORTHERN DISTRICT OF OHIO

EASTERN DIVISION

In re NATIONAL PRESCRIPTION OPIATE LITIGATION	No. 1:17-md-2804
	Judge Dan A. Polster
This Document Relates To:	
Track One Cases.	

PLAINTIFFS' MEMORANDUM IN OPPOSITION TO DEFENDANTS' MOTION TO EXCLUDE SETH WHITELAW'S OPINIONS AND PROPOSED TESTIMONY

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I. INTRODUCTION

Defendants[1] seek to exclude, under Federal Rule of Evidence 702 and *Daubert v. Merrell Dow Pharm., Inc.,* 509 U.S. 579 (1993), the opinions of Dr. Seth B. Whitelaw on the subject of the relevant standards applicable to corporate and controlled substances compliance programs for the pharmaceutical industry, the application of those standards to manufacturers and distributors of controlled substances and the effectiveness of Defendants' compliance programs. Defendants' challenges to Dr. Whitelaw's opinions are entirely lacking in merit.

As set forth in detail below, Dr. Whitelaw is a highly credentialed attorney, compliance officer, compliance consultant and professor who has extensive experience in the life science compliance industry in which he offers testimony in this case. Defendants mischaracterize Dr. Whitelaw's opinions as being confined to suspicious order monitoring, but in fact, he conducted a holistic assessment of Defendants' compliance programs, of which their anti-diversion efforts were a part. Contrary to Defendants' assertions, Dr. Whitelaw's expertise includes anti-diversion programs.

Dr. Whitelaw has provided Defendants with a detailed expert report setting forth each of his opinions and the specific bases for his opinions. Defendants erroneously attack his methodology, contending that no one in the industry uses the Federal Sentencing Guidelines ("FSGs") or the Office of Inspector General's Compliance Program Guidance ("OIG Guidance") in developing and evaluating anti-diversion programs. They further contend that Dr. Whitelaw's compliance maturity model is an "unverified methodology," despite the fact that it is a tool widely used by compliance professionals, including Dr. Whitelaw. In reality, Defendants themselves both expressly and implicitly incorporate the FSGs, OIG Guidance and maturity models as part of their compliance programs,

[1] References to "Defendants" collectively refer to McKesson Corporation ("McKesson"), AmerisourceBergen Drug Corporation ("ABDC"), CVS Rx Services, Inc., CVS Indiana, LLC (collectively, "CVS"), Walgreen Co., Walgreen Eastern Co. (collectively, "Walgreens") and Mallinckrodt plc, Mallinckrodt LLC and SpecGx LLC (collectively, "Mallinckrodt").

including their anti-diversion efforts. Furthermore, numerous publications and textbooks support that compliance professionals use the FSGs and maturity models in assessing compliance, and recent settlements confirm that the Department of Justice ("DOJ") relies on the elements contained in the FSGs in assessing anti-diversion compliance specific to opioids (*see infra* at 9-10). At no point do Defendants explain why the FSGs or OIG Guidance are unreliable tools to assess compliance, nor can they.

In sum, Dr. Whitelaw is fully qualified to offer his opinions, and his methodologies are reliable and well accepted. Dr. Whitelaw's testimony will assist the jury by providing important background and context on the complex regulatory scheme applicable to opioid manufacturers and distributors. His opinions should be permitted in full.

II. LEGAL STANDARDS

Plaintiffs are separately filing herewith Plaintiffs' *Daubert* Roadmap Brief setting forth the legal standards generally applicable to *Daubert* challenges, and Plaintiffs adopt and incorporate herein by reference that memorandum.

III. ARGUMENT

A. Dr. Whitelaw Is Well Qualified to Opine on the Proper Structure of a Compliance Program and the Deficiencies in the Compliance Programs He Analyzed in This Case

Dr. Whitelaw offers opinions concerning the proper components of a compliance program for pharmaceutical manufacturers and distributors and provides an in-depth assessment of Defendants' compliance programs. Using his 30 years of experience in designing, building and assessing the effectiveness of corporate compliance programs, Dr. Whitelaw describes in his report the following elements of an effective compliance program: (1) Organization and Resources; (2) Due Diligence; (3) Written Standards; (4) Training & Communication; (5) Monitoring, Auditing, & Investigations; (6) Corrective Actions; (7) Enforcement; and (8) Periodic Risk Assessment. Report of

Dr. Seth B. Whitelaw, Dkt. #2000-26 at 24.[2] After Dr. Whitelaw describes the elements of "what good looks like," he then offers a Compliance Maturity and Program Effectiveness Model ("Model") for measuring compliance, derived from existing models widely used by him and other trained compliance professionals. *Id.* at 43-44.

While Defendants' motion casts Dr. Whitelaw's opinions as being singularly focused on suspicious order monitoring, in fact, Dr. Whitelaw's assessment is much broader than that. Dr. Whitelaw undertook a comprehensive examination of Defendants' compliance programs as a whole, which included their suspicious order monitoring efforts, but was not confined to just those efforts. This holistic compliance assessment was done with the overall aim of determining what is required of reasonable drug manufacturers and distributors to prevent diversion of opioids and to gauge whether Defendants did those things. Ex. 1 (Whitelaw Tr.) at 482:14-23. As described below, this sort of holistic assessment is consistent with those conducted by Dr. Whitelaw over his 30-year compliance career.

Dr. Whitelaw is more than qualified to assess Defendants' compliance programs and to offer opinions concerning their respective deficiencies. Under Rule 702, an expert's opinion is admissible if the expert is qualified by "knowledge, skill, experience, training, or education." *U.S. ex rel. Tenn. Valley Auth. v. 1.72 Acres of Land in Tenn.,* 821 F.3d 742, 749 (6th Cir. 2016).[3] For the past 30 years, Dr. Whitelaw has worked as a "food and drug attorney, compliance officer, compliance consultant and professor" teaching law students as part of Mitchell Hamline School of Law's Healthcare Compliance Certificate program. Whitelaw Rep., Dkt. #2000-26 at 1. Since 1993, Dr. Whitelaw has

[2] Citations, internal quotations and footnotes are omitted and emphasis is added throughout, unless otherwise noted.

[3] *See also Rheinfrank v. Abbott Labs., Inc.*, 2015 WL 13022172, at *14 (S.D. Ohio Oct. 2, 2015), *aff'd*, 680 F. App'x 369 (6th Cir. 2017) (expert qualified to opine regarding defendants' compliance with FDA regulations; questions regarding expert's experience go to credibility and may be addressed on cross-examination).

"designed, built, and run four separate corporate compliance programs for both pharmaceutical and medical device manufacturers (C.R. Bard, Inc., SmithKline Beecham Pharmaceuticals NA, GlaxoSmithKline R&D, Misonix, Inc.)." *Id.* From 2011 to 2015, Dr. Whitelaw worked for Deloitte & Touche LLP ("Deloitte") as a Director focused on various aspects of compliance. *Id.* at 280. From 2015 to present, Dr. Whitelaw has run his own compliance consulting company, which focuses on providing "practical, pragmatic compliance and integrity services." *Id.* at 279. From 2015 to the present, Dr. Whitelaw has also acted as editor for the monthly publication *Policy & Medicine Compliance Update. Id.*

Contrary to Defendants' contentions, Dr. Whitelaw also possesses specific expertise relevant to anti-diversion efforts. While working at Deloitte, Dr. Whitelaw was a key member of a team that was asked by Henry Schein – a distributor defendant in this case – to propose enhancements that could be made to its anti-diversion program for controlled substances. *See* Ex. 2 (HSI-MDL-00423205). The fact that Henry Schein and Deloitte sought this input from Dr. Whitelaw speaks volumes as to his experience in this field. Dr. Whitelaw also has extensive experience designing and overseeing sample accountability programs, which, from a diversion perspective, are substantially equivalent to anti-diversion programs for controlled substances. Ex. 1 (Whitelaw Tr.) at 63:20-64:11, 73:2-24; Whitelaw Rep., Dkt. #2000-26 at 4. Additionally, in order to supplement this experience, Dr. Whitelaw consulted with James Rafalski, a former DEA diversion investigator and expert witness for Plaintiffs in this case, concerning various aspects of controlled substance compliance from the perspective of someone with experience working at DEA. *See* Whitelaw Rep., Dkt. #2000-26 at 4. In short, Dr. Whitelaw has the requisite knowledge and experience to offer his opinions. *See In re Heparin Prods. Liab. Litig.*, 803 F. Supp. 2d 712, 747 (N.D. Ohio 2011), *aff'd sub nom. Rodrigues v. Baxter Healthcare Corp.*, 567 F. App'x 359 (6th Cir. 2014) ("So long as the expert has some specialized knowledge as a

result of training or experience relevant to the opinions he offers, his testimony will meet the qualification requirement.").

B. Dr. Whitelaw Applied Sound Methodology in Formulating His Opinions

1. Dr. Whitelaw's Use of the Federal Sentencing Guidelines and Office of Inspector General's Guidance Is Proper

Defendants also attack the methodology employed by Dr. Whitelaw to create the components of a model compliance program and to analyze Defendants' compliance programs. *See* §III.A., *supra*. Defendants focus their methodology criticism on Dr. Whitelaw's use of the elements of an effective compliance program derived from the FSGs and OIG Guidance.[4] While Defendants misconstrue the methodology employed by Dr. Whitelaw, there can be no doubt that his reliance on both the FSGs and the OIG Guidance was appropriate.

First, the use of the FSGs as the baseline framework for his analysis is consistent with Dr. Whitelaw's practice outside of litigation. *See* Ex. 1 (Whitelaw Tr.) at 24:19-25:18, 96:2-11. An expert may "draw a conclusion from a set of observations based on extensive and specialized experience." *Kumho Tire Co., Ltd. v. Carmichael*, 526 U.S. 137, 156 (1999).[5]

As Dr. Whitelaw further noted, his approach is not unique in the compliance field. As he testified in his deposition:

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[4] While it is certainly true that Dr. Whitelaw relied on both of these standards as part of his overall assessment and that the FSGs served as the overall framework for his analysis, those were by no means the only standards or guidelines he used. As Dr. Whitelaw's report makes clear, in addition to the FSGs and the OIG Guidance, he also considered provisions of the Affordable Care Act and DOJ and HCCA/OIG Program Effectiveness Guidance documents. *See* Whitelaw Rep., Dkt. #2000-26 at 12-13. Moreover, Dr. Whitelaw augmented his consideration of these general compliance guidance documents by also relying on additional information specific to controlled substances. To this end, he also considered and relied upon the Controlled Substances Act ("CSA"), DEA's implementing regulations, DEA guidance, the decision in *Masters Pharm., Inc. v. DEA*, 861 F.3d 206 (D.C. Cir. 2017), and relevant industry guidance documents. *See id.* at 13-22.

[5] *In re Gadolinium-Based Contrast Agents Prods. Liab. Litig.*, 2010 WL 1796334, at *6 (N.D. Ohio May 4, 2010), *opinion modified on reconsideration*, 2010 WL 5173568 (N.D. Ohio June 18, 2010), *aff'd in part sub nom. Decker v. GE Healthcare Inc.*, 770 F.3d 378 (6th Cir. 2014) (expert theory reliable where experts' research related "not only to their review of the literature but to matters growing naturally or necessarily out of research they have conducted independent of this litigation").

> The guidelines [FSGs] are the basic framework. They are where everybody starts. It's where industry starts. It's where compliance professionals start. It's where good companies start, et cetera. It is the baseline. It has become the de facto set of standards that you start with when you're looking at and assessing corporate compliance programs. . . . So those standards, although they are embodied in that section, are actually the basis that we use day in and day out as consultants, compliance professionals, et cetera, to do our job.

Ex. 1 (Whitelaw Tr.) at 142:13-24, 143:23-144:4.

Defendants' attempt to portray Dr. Whitelaw's methodology as being inconsistent with the methodology he employs outside of litigation is without merit. The only evidence Defendants use to support this faulty position is an article written by Dr. Whitelaw in March 2018. *See* Memorandum of Points and Authorities in Support of Defendants' Daubert Motion to Exclude the Opinions of Seth B. Whitelaw ("Mem.") at 11-12. However, as Dr. Whitelaw noted in his deposition, his position on the utility of government guidance documents has been consistent over time and has not been altered by his work in this case. *See* Ex. 1 (Whitelaw Tr.) at 281:1-282:18.

Second, Defendants argue that "[n]either DEA nor industry participants – nor anyone else – uses the [FSGs] to evaluate suspicious order monitoring programs." Mem. at 1. In truth, Defendants themselves are among the industry participants who use these tools as a basis for their compliance programs, including anti-diversion compliance. For example, in a slide deck titled "Overview of McKesson's Controlled Substances Monitoring Program," McKesson's regulatory department included a slide titled "The Definition of an Effective Compliance Program." Ex. 3 (MCKMDL00336304) at 310. On the slide, McKesson noted, "[t]he [f]ederal government defined the elements of an effective compliance program in the [FSGs] in the 1990s." *Id.* This slide also includes a circular chart that depicts the very same eight elements from the FSGs that Dr. Whitelaw used as the framework for his general analysis. *Id.*

But McKesson is not alone in expressly adopting the FSGs and/or OIG Guidance as being vital tools in assessing their own compliance. According to a 2016 ABDC Corporate Security &

Regulatory Affairs presentation, "[a] key component of our program is our global Code of Ethics, which meets U.S. federal sentencing guidelines and ***applies to all businesses***."[6] Similarly, Mallinckrodt has stated in its public 10-K filings that:

> In order to systematically and comprehensively mitigate the risks of non-compliance with regulatory requirements described within this Item 1. Business, we have developed what ***we believe to be a robust compliance program based on the April 2003 Office of the Inspector General ("OIG") Compliance Program Guidance for Pharmaceutical Manufacturers, the U.S. Federal Sentencing Guidelines***, the Pharmaceutical Research and Manufacturers of America Code on Interactions with Healthcare Professionals, the Code of Ethics of the Advanced Medical Technology Association, the U.K. Anti-Bribery guidance, and ***other relevant guidance from government and national or regional industry codes of behavior***.[7]

Likewise, Walgreens' "Compliance Program Overview 2017" states that "[t]he elements of Walgreens compliance program mirror the requirements of effective compliance programs recommended by the Office of the Inspector General (OIG) and the [FSGs]."[8] Similarly, in a 2009 presentation by Cardinal's Senior Vice President of Corporate Ethics and Compliance, a slide titled "Legal/quasi-legal requirements" includes both the FSGs and the OIG Guidance. Ex. 7 (April 22, 2009 presentation). Finally, CVS' current Code of Conduct uses the FSGs as one tool to assess compliance in the context of Medicare-related programs. Ex. 8 (CVS Code of Conduct) at 29.

Furthermore, Defendants' own audits of their suspicious order monitoring ("SOM") programs also used elements contained in the FSGs.[9] For example, a McKesson internal audit dated

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6 Ex. 4 (ABDCMDL00273319) at slide 19.

7 Ex. 5 (MNK-T1_0005141469) at 484.

8 Ex. 6 (WAGMDL00444987) at 988.

9 Additionally, Defendants' own suspicious order monitoring experts use many, if not all, of the same elements comprising the FSGs to assess Defendants' SOM programs. For example, ABDC's SOM expert, Robert Buskey, discussed ABDC's organization and resources (*see, e.g.*, Report of Robert L. Buskey, Dkt. #1939-4 at 16, 23-35) (describing ABDC's "dedicated diversion control team," which was "in addition to the existing security team," and stating that ABDC "continued to enhance and improve its due diligence efforts, consistent with a compliance program that seeks to evolve and improve" with "key hires"); due diligence (*see, e.g.*, *id.* at 21-23) (discussing ABDC's "rigorous" due diligence process); training (*see, e.g.*, *id.* at 16, 18) (describing annual training required of ABDC's compliance employees); monitoring, auditing and investigations (*see, e.g.*, *id.* at 16, 22-23) (describing the "three pillars" of ABDC's diversion control program and

October 8, 2008, created for the purpose of "evaulat[ing] the effectiveness of CSMP policies, procedures, and controls," discussed organization and resources;[10] due diligence;[11] written standards;[12] training and communication;[13] monitoring, auditing and investigation;[14] corrective actions and enforcement;[15] and, finally, periodic risk assessment.[16]

Third, authoritative publications and textbooks support that compliance professionals routinely use the FSGs in assessing compliance. For example, The Society of Corporate Compliance and Ethics ("SCCE")[17] first published its treatise, *Compliance 101*, in 2008 to provide information on how to build and maintain an effective compliance program.[18] In discussing the components of an effective compliance program, the authors highlight the FSGs and their elements, commenting that "they make up the ***backbone*** of a good compliance program." Ex. 11 at 8. Furthermore, they note

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ABDC's internal and external audits); corrective actions and enforcement (*see, e.g.*, *id.* at 21, 30) (discussing ABDC's "Do Not Ship" list of customers to which it would no longer ship controlled substances or declined to onboard following a new customer due diligence investigation); and periodic risk assessments (*see, e.g.*, *id.* at 29 (stating that ABDC now conducts an annual self-evaluation process that "allows ABDC to modify its system as needed to maintain sufficient and effective controls in a changing environment").

[10] *See, e.g.*, Ex. 9 (MCKMDL00721376) at 379, 383-384, 386 (recommending that management modify policies and procedures to provide consistent guidance to distribution centers and that management clarify employee responsibilities).

[11] *Id.* at 386, 388 (noting that failure to maintain due diligence records is a compliance risk and that corrective action be taken to address employee's inappropriate access to modify threshold values).

[12] *Id.* at 380-381 (noting a key issue identified during audit was inconsistent documentation and lack of clear and consistent standard operating procedures).

[13] *Id.* at 386 (recommending better management communication and that training be provided to employees).

[14] *Id.* at 382-383 (noting deficiencies in suspicious order monitoring and investigations).

[15] *Id.* at 381, 383, 388 (noting remedial action taken as a result of issues found in audit).

[16] *Id.* at 378-380 (discussing background and scope of Internal Audit's assessment of McKesson's SOM program).

[17] The SCCE was founded in 2004 with the mission "to champion ethical practice and compliance standards and to provide the necessary resources for ethics and compliance professionals and others who share these principles." According to its website, the SCCE currently has 7,500+ members across a variety of industries, including healthcare. *See* Ex. 10, SCCE, *About SCCE*, https://www.corporatecompliance.org/about-scce (last visited July 23, 2019).

[18] *See* Ex. 11 (SCCE 2008) at 8.

that "[t]he government believes that every effective compliance program begins with a formal commitment to these seven basic elements." *Id.*

Published by the Health Care Compliance Association ("HCCA"),[19] the Health Care Compliance Professional's Manual ("HCCP Manual") is one of the leading textbooks used by compliance professionals and faculty who teach health care compliance.[20] Unsurprisingly, the HCCP Manual devotes a significant section to discussing the FSGs. According to the HCCP Manual, the FSGs "represent a kind of watershed" because:

> their definition of "an effective" corporate compliance program has provided the leading framework for an ongoing national dialogue – through conferences, books, newsletters, and best practice forums – on how to build compliance programs that really work. . . . In short, the federal Sentencing Guidelines compliance program standards have been the "***currency of the realm***" in compliance circles over recent years.[21]

Fourth, recent settlements confirm that the DOJ relies on the elements contained in the FSGs in assessing anti-diversion compliance specific to opioids. One such example is the compliance addendum, which was an element of the 2017 settlement agreement between McKesson and the DOJ for opioid-related Controlled Substances Act violations. Notably, the "Compliance Obligations" section of the compliance addendum directly tracks the elements of the FSGs. Specifically, the addendum requires the maintenance of a compliance department with a set list of high-ranking

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[19] The HCCA was established in 1996 and serves more than 12,000 members across the U.S. to enable "the lasting success and integrity of those working in, working with or supporting healthcare organizations." *See* Ex. 12, HCCA, *About Us*, https://www.hcca-info.org/about-hcca/about-hcca (last visited July 23, 2019).

[20] *See* Roy Snell, *Foreword*, in Health Care Compliance Professional's Manual (2016 Edition) ("This manual is the most comprehensive written compilation of expert opinion in our profession [and] [i]t is updated on a regular basis."). Ex. 13.

[21] Gabriel Imperato and Anne Novick Brannan, "The Federal Sentencing Guidelines: A Practical Overview of Their Background, Intent, and Implications," in *Health Care Compliance Professional's Manual* ¶30,180 (2016 Edition). Ex. 13. Additionally, the Manual notes, "[a] compliance program that meets the seven elements has become an expectation of the OIG, as well as the Department of Justice (DOJ), CMS, and potential buyers, investors, and lenders." *Id.* at ¶30,220. Therefore, as the authors point out, "[h]ealth care companies, as well as all businesses, should continue assessing their compliance programs to make sure they are effective for purposes of the [FSGs] because this remains '***the gold standard***.'" *Id.* at ¶30,250.

individuals required to be included within the department, which coincides directly with the organization and resources elements of the FSGs. Ex. 14 (McKesson Compliance Addendum) at 3-6. The section of the compliance addendum titled "Compensation and Independence" tracks directly with the "due diligence (*i.e.*, avoiding bad actors)" element of the FSGs, as discussed in Dr. Whitelaw's report. *Id.* at 6-7; Whitelaw Rep., Dkt. #2000-26 at 24. The next section of the compliance addendum is titled "Written Standards," which mirrors the element of the FSGs by that very same name. Ex. 14 (McKesson Compliance Addendum) at 7-8; Whitelaw Rep., Dkt. #2000-26 at 24. The following section of the addendum is titled "Training and Awareness," which again directly tracks the "Training and Communication" element of the FSGs. Ex. 14 (McKesson Compliance Addendum) at 8-9; Whitelaw Rep., Dkt. #2000-26 at 24. The next two sections of the McKesson compliance addendum are titled "Non-Retaliation Policies" and "Ethics Hotlines," which again closely mirror the FSG's "corrective actions" and "enforcement" requirements. Ex. 14 (McKesson Compliance Addendum) at 9-10; Whitelaw Rep., Dkt. #2000-26 at 24. Finally, the compliance addendum outlines various investigatory and reporting requirements, which coincide with the "monitoring, auditing, & investigations" requirement from the FSGs, as described in Dr. Whitelaw's report. Ex. 14 (McKesson Compliance Addendum) at 10-12; Whitelaw Rep., Dkt. #2000-26 at 24. The similarities between the FSGs and the McKesson Compliance Addendum are telling and provide further compelling evidence of the validity of Dr. Whitelaw's methodology.[22]

Finally, while Defendants criticize Dr. Whitelaw's reliance on the FSGs and the OIG Guidance, Defendants completely fail to explain why those guidelines are in any way an unreliable

[22] Additionally, the recently settled case involving the Rochester Drug Co-Operative ("RDC") involved a pharmaceutical distributor's anti-diversion efforts concerning opioids. *See* Ex. 15 (DOJ and RDC Deferred Prosecution Agreement) at 1 (Apr. 22, 2019). While the DOJ did not expressly reference the FSGs by name in its agreement with RDC, the prosecutors nevertheless used the elements of an effective compliance program outlined by the FSGs to evaluate whether RDC's compliance program met its statutory obligations under the CSA. To this point, the DOJ assessed the company's culture of compliance, resourcing for compliance, its policies and procedures and employee incentives and training, all of which are components of an effective compliance program as set out in the FSGs. *See id.* at Exhibit C (Statement of Facts).

tool to assess corporate compliance, including anti-diversion compliance; nor do they offer an appropriate alternative. As noted above, since these guidelines are used by Defendants themselves, the DOJ and compliance professionals everywhere, it is readily apparent why Defendants offer no such specific criticisms. However, their failure to identify why either of these guidelines is an unreliable tool to use to assess compliance is fatal to their motion. A review of the elements employed by Dr. Whitelaw leads to the inescapable conclusion that they are reasonable measures for assessing compliance programs whether they are derived from the FSGs, the OIG Guidance, or some other source.

2. Dr. Whitelaw's Compliance Maturity Model Has Been Used by Him During His 30-Year Compliance Career and by Other Trained Compliance Professionals

Defendants also contend that Dr. Whitelaw created "solely for purposes of this litigation" (Mem. at 12) the Model found in Figure 2 of Dr. Whitelaw's report, which sets forth the best approximation of a standardized framework for measuring compliance effectiveness. Whitelaw Rep., Dkt. #2000-26 at 43. In fact, the Model has been used by Dr. Whitelaw outside of his work in this litigation[23] and was derived from similar models used by other compliance professionals. *See Piskura v. Taser Int'l Inc.*, 2013 WL 3967323, at *10-*11 (S.D. Ohio July 31, 2013) (rejecting argument that expert opinion was "made-for-litigation," finding that expert's anticipated testimony "flows naturally from his past technical work in safety management and risk assessment").

Contrary to Defendants' assertion that the Model is an "unverified scoring methodology" that was created "with no citation to any publication or accepted practice" (Mem. at 5), Dr. Whitelaw's Model was derived directly from existing models and was adapted from information widely used by

[23] Defendants misleadingly cite to Dr. Whitelaw's deposition testimony in support of their argument that Dr. Whitelaw never "used [the Model] to evaluate an SOM program," but they omit the fact that Dr. Whitelaw testified that "it is a standard compliance maturity model that [he has] used to evaluate compliance programs." Ex. 1 (Whitelaw Tr.) at 715:8-14.

compliance professionals for purposes of evaluating the extent to which a compliance program has become an integrated part of an organization's operations. *See* Ex. 1 (Whitelaw Tr.) at 422:13-423:3:

> Q. Figure 2 on page 43, the maturity scale, that's the model that you made up for figuring out where in its maturity level or life span a company is with respect to compliance. Is that a roughly fair statement?
>
> A. No, I don't think it's a fair statement. It's something – you're characterizing it as something that I made up. No, it's something that is in general use among compliance professionals and others out there.

Upon further questioning, Dr. Whitelaw described compliance professionals who used similar versions of the Model, including "see[ing] it in use in [his] time in Deloitte." *Id.* at 423:5-424:19. In fact, Defendants' own documents belie their assertion that Dr. Whitelaw's Model is "untethered to any real-world experience." Mem. at 12. According to a June 2009 presentation titled "Cardinal Health Operations, Compliance and Information Technology," "Cardinal Health . . . asked Deloitte to provide thoughts on it's [sic] strategic supply chain initiatives." Ex. 16 (CAH_MDL2804_03415292) at 294. In it, Deloitte recommended that "[t]he alignment between IT Strategy and Supply Chain Strategy at Cardinal Health should progress towards the leading stage" and went on to present a chart of four different stages of business strategy and IT Alignment ranging from "lagging" to "leading."[24]

Similar maturity models can also be found in the published literature. *See, e.g.*, Ex. 18 (describing a five-stage corporate responsibility maturity model and highlighting a similar model created by Novo Nordisk); Ex. 19 (outlining a five-stage corporate responsibility maturity model, which includes Denier, Complier, Risk Mitigator, Opportunity Maximizer and Champion); Ex. 20 (describing a five-stage corporate maturity model that is meant to be a framework to "[u]se . . . . to

[24] Furthermore, Cardinal Health used a so-called maturity model in a presentation dated May 8, 2008, titled "Suspicious Order Monitoring – Objective Evidence, Customer Segmentation and Applicable SOM Rules." Therein, Cardinal Health noted a "[g]oal [of] develop[ing] a tool to assess 'risk' of diversion by customer channel, and within the channel, by customer." Ex. 17 (CAH_MDL2804_00227735) at 736. The presentation further discussed a "Customer Assessment Tool – Maturity Model," which, just like Dr. Whitelaw's model, sets out a framework outlining characteristics that distinguish a customer assessment tool from one that is "lagging" to one that is "best in class." *Id.* at 740.

make the business case for starting or continuing movement from siloed reactive, compliance-driven, processes to an integrated GRC [Global Risk and Compliance] program in [the] organization."). *Id.* at 4.[25]

Thus, it is clear from Dr. Whitelaw's testimony and the existence of similar compliance maturity models in use by other experts in the field that his Model is premised on a reliable methodology that was not created solely for the purpose of litigation.

C. Dr. Whitelaw Does Not Opine on the Ultimate Legal Issues in the Case

Defendants also erroneously contend that Dr. Whitelaw offers opinions on the ultimate legal issues in the case. In this regard, Defendants mischaracterize Dr. Whitelaw's report as opining on "whether certain defendants' suspicious order monitoring systems complied with applicable statutes and regulations." Mem. at 13. Federal Rule of Evidence 704(a) states that "[a]n opinion is not objectionable just because it embraces an ultimate issue." Although a witness may not testify to a legal conclusion, an expert testifying about factual issues may state opinions that suggest the answer to the ultimate issue. *Berry v. City of Detroit*, 25 F.3d 1342, 1353 (6th Cir. 1994).[26]

Here, Dr. Whitelaw does not opine on whether Defendants have acted contrary to any specific laws or regulations, including the CSA. Instead, Dr. Whitelaw offers opinions concerning the proper elements of a compliance program for a reasonable pharmaceutical manufacturer and distributor and offers an assessment of Defendants' compliance programs based upon those elements. Dr. Whitelaw's

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[25] Additionally, beyond simply developing a maturity model, the OCEG has used its model to conduct benchmarking surveys. The 2015 Maturity Survey, for example, examined "how organizations are taking varying approaches to GRC from the siloed to the fully integrated and measures the satisfaction and confidence organizations have as a result." Ex. 21, OCEG, *2015 GRC Maturity Survey* at 3 (2015). The survey included responses from 596 worldwide participants across a variety of industries and company sizes. *Id.* at 7-8.

[26] *See also Allied Erecting & Dismantling Co., Inc. v. Genesis Equip. & Mfg., Inc.*, 2009 WL 8592874, at *4 (N.D. Ohio Aug. 12, 2009) (exclusion of trade secret expert not warranted where his "opinions on certain subsidiary components of the overall issue . . . do not invade the province of the jury; rather, his opinions will aid the jury's determination as to whether Allied's information constitutes a trade secret").

testimony will assist the jury by providing important background and context on the complex regulatory scheme applicable to opioid manufacturers and distributors, which is likely unfamiliar to a layperson. Federal courts across the country, including courts in this circuit, routinely permit expert testimony related to such complex regulatory areas to assist jurors' understanding.[27] As an expert in the design, implementation and operation of compliance programs, Dr. Whitelaw provides valuable guidance to assist the jury in understanding the relevant standards applicable to Defendants' corporate compliance and anti-diversion programs and the effectiveness of Defendants' corporate compliance programs.

IV. CONCLUSION

It is clear that Dr. Whitelaw's opinions and analysis would provide valuable information to assist the trier of fact in evaluating the conduct of each defendant and the steps taken or not taken to be in compliance with the CSA and regulations. For the foregoing reasons, this Court should deny in its entirety Defendants' motion to exclude Dr. Whitelaw's opinions and testimony.

Dated: July 31, 2019

Respectfully submitted,

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[27] *See, e.g.*, *Mathews v. Novartis Pharm. Corp.*, 2013 WL 5780415, at *24 (S.D. Ohio Oct. 25, 2013) (expert not permitted to offer legal conclusions but allowing expert to offer testimony about what the FDA regulations require of drug manufacturers); *In re Mirena IUD Prods. Liab. Litig.*, 169 F. Supp. 3d 396, 479 (S.D.N.Y. 2016) ("[B]ecause this case involves state law claims of negligence and strict liability, Dr. Parisian's testimony regarding compliance with FDA regulations does not usurp the role of the jury, but rather merely helps them understand a complicated statutory framework."); *see also In re Depakote*, 2015 WL 4775868, at *8 (S.D. Ill. Feb. 13, 2015) (expert permitted to opine on regulatory framework, applicable regulations and regulatory implications of the defendant's conduct due to the complex nature of the drug labeling process and procedures).

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